

**REMARKS**

This is in response to the Advisory Action mailed May 24, 2006. A Notice of Appeal had been filed on April 19, 2006, which starts the calendar for response. Thus Applicants request a three-month extension of time for response and are concurrently filing an RCE herewith in order to have the amendments and remarks herein considered.

Claims 1-19, 21-22 and 29-46 are under consideration in the present application. By this amendment Claims 1-6, 8-19, 21-22, 29-38 and 40-46 have been amended and Claims 7 and 39 have been cancelled and the subject matter thereof incorporated into other claims.

Support for the amendments may be found throughout the specification, particularly the examples, and the figures.

Applicants note with appreciation the Examiner's withdrawal of the rejection of Claims 1-19, 21-22 and 29-46 as indefinite under 35 USC §112 ¶2 regarding recitation of other components in the sample.

The Examiner has maintained the scope of enablement rejection of Claims 1-19, 21-22 and 29-46 under 35USC §112 ¶1 for utilizing any/all other body fluids, e.g., urine, or utilizing a polypeptide having a MW in the range of 1000-100,000 Da. In regard to the Examiner's prior rejection, Applicants had pointed to paragraphs 124-127 for support in their prior response. Applicants apologize for the Examiner's confusion – the paragraph numbering comes from Applicants' published application (US2004/0171026

A1) corresponding to the present application. The referenced arguments came from Example 5.

By the present amendment, Applicants have amended the claims to provide that the tested body fluid is selected from cerebrospinal fluid (CSF), blood, plasma or serum. Support for the use of CSF, plasma, blood and serum is clearly found in the detailed description and examples in the specification. In addition, those skilled in the art also would recognize that blood, plasma and serum may be utilized interchangeably for such assays. Thus, in view of the amendments, the rejection of the claims for lack of sufficient scope of enablement as to the body fluid should be withdrawn.

Likewise, the claims have been amended to list the particular molecular weights of the polypeptides disclosed and exemplified in the specification, whose differential expression can be used to diagnose TSE. The examples and the figures clearly demonstrate the differential expression of the recited polypeptides in subjects with TSE compared to reference samples from subjects with no TSE. Thus, in view of the amendments to the claims to indicate the specific molecular weights of polypeptides (mass spectrometry peaks) differentially expressed in TSE, Applicants maintain that the rejection for lack of scope of enablement should be withdrawn.

The Examiner has maintained the rejection of Claims 1-19, 21-22 and 29-46 as indefinite under 35 USC §112 ¶2. The Examiner argues that the language “determining whether . . . consistent with a diagnosis of TSE” is indefinite. Applicants have amended the claims consistent with the Examiner’s suggestion to recite that an increase or decrease

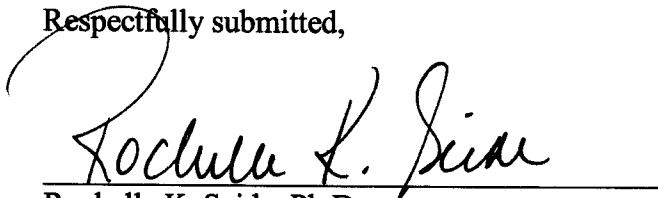
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Response dated August 22, 2006

in the polypeptide in the body fluid of the subject indicates TSE. In view of these amendments, Applicants request withdrawal of this indefiniteness rejection.

In view of the amendments to the claims and the remarks herein, Applicants request reconsideration and allowance of the pending claims. Applicants are filing an RCE concurrently herewith to ensure full reconsideration of the amendments to the pending claims. A Notice of Allowance is respectfully requested.

Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300, **referencing Docket Number 108140.00030.**

Respectfully submitted,

A handwritten signature in cursive script, reading "Rochelle K. Seide", is written over a horizontal line.

Rochelle K. Seide, Ph.D.  
Registration No. 32,300  
ARENT FOX PLLC  
1675 Broadway  
New York, NY 10019  
Tel. No. (212) 484-3945  
Fax No. (212) 484-3990  
Customer No. 38485

# **FEE CALCULATION**

Any additional fee required has been calculated as follows:

X If checked, "Small Entity" status is claimed.

	(Column 1)	(Column 2)	(Column 3)	SMALL ENTITY			LARGE ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADD'L FEE	OR	RATE	ADD'L FEE
TOTAL CLAIMS	37 MINUS	47	= 0	x \$25	\$0.00		x \$50	\$
INDEP CLAIMS	12 MINUS	17	= 0	x \$100	\$0.00		x \$200	\$
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ \$180	\$0.00	OR	+ \$360	\$
					\$0.00			\$

The U.S. Patent and Trademark Office is hereby authorized to charge and deficiency or credit any overpayment of fees associated with this communication to Deposit Account No. 01-2300 referencing docket number 108140.00030.